

Listing of Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A solid dose controlled release nanoparticulate composition comprising:
 - (a) a nanoparticulate drug composition comprising a poorly soluble nanoparticulate drug to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate drug, wherein the nanoparticulate drug has an effective average particle size of less than about 1000 nm, wherein at least 50% of the drug particles have an average particle size of less than about 1000 nm when measured by light scattering techniques, and
 - (b) at least one pharmaceutically acceptable **high molecular weight** rate-controlling polymer, wherein:
 - (i) the **high molecular weight** rate-controlling polymer is integrated in a rate-controlling matrix with the nanoparticulate drug composition or coats the nanoparticulate drug composition, and
 - (ii) the controlled release nanoparticulate composition provides controlled release of the nanoparticulate drug for a time period ranging from about 2 to about 24 hours.
2. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the effective average particle size of the nanoparticulate drug is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm, wherein at least 50% of the drug particles have an average particle size of less than about 800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

3. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 1, wherein the concentration of the **high molecular weight** rate controlling polymer is from about 5 to about 95% (w/w).

4. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 3, wherein the concentration of the **high molecular weight** rate controlling polymer is from about 10 to about 65% (w/w).

5. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1 additionally comprising a binder agent in an amount of from about 0.1 to about 10% (w/w).

6. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1 additionally comprising a lubricant in an amount of from about 0.1 to about 10% (w/w).

7. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 6, wherein the lubricant is selected from the group consisting of magnesium stearate, hydrogenated vegetable oil, and stearic acid.

8. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the solid dose formulation is made by wet granulation.

9. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1 formed by wet granulation, wherein water is added to the nanoparticulate drug, surface stabilizer, and polymer to form granules prior to forming the solid dose of the controlled release formulation.

10. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 1, wherein the **high molecular weight** rate-controlling polymer is selected from the group consisting of gum arabic, agar, guar gum, cereal gums, dextran, casein, gelatin, pectin, carrageenan, waxes, shellac, hydrogenated vegetable oils, polyvinylpyrrolidone, hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), hydroxypropyl methylcellulose (HPMC), sodium carboxymethylcellulose (CMC), poly(ethylene) oxide, alkyl cellulose, ethyl cellulose, methyl cellulose, carboxymethyl

cellulose, hydrophilic cellulose derivatives, polyethylene glycol, polyvinylpyrrolidone, cellulose acetate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl acetate phthalate, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, polyvinyl acetaldiethylamino acetate, poly(alkylmethacrylate), poly(vinyl acetate), polymers derived from acrylic or methacrylic acid and their respective esters, and copolymers derived from acrylic or methacrylic acid and their respective esters.

11. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 10, wherein the **high molecular weight** rate-controlling polymer is hydroxypropylmethyl cellulose (HPMC).

12. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 10, wherein the **high molecular weight** rate-controlling polymer is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.

13. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the poorly water soluble nanoparticulate drug is present in an amount of from about 1 µg to about 800 mg.

14. (Previously Presented) A solid dosage form comprising a controlled release nanoparticulate composition according to claim 1, wherein the dosage form is in tablet form, multiparticulate form, or in a powder form.

15. (Previously Presented) The solid dosage form of claim 14, wherein the nanoparticulate drug and at least one auxiliary excipient are compressed into tablet form prior to coating with a rate controlling polymer.

16. (Currently Amended) The solid dosage form of claim 14, wherein the nanoparticulate drug, the **high molecular weight** rate controlling polymer and at least one auxiliary excipient are compressed to form a controlled release matrix tablet.

17. (Previously Presented) The solid dosage form of claim 16, wherein the controlled release matrix is coated with a rate controlling polymer.

18. (Previously Presented) The solid dosage form of claim 14, wherein the nanoparticulate drug and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with a rate controlling polymer.

19. (Currently Amended) The solid dosage form of claim 14, wherein the nanoparticulate drug is dispersed in the **high molecular weight** rate controlling polymer material and compressed into the form of a multilayer tablet.

20. (Previously Presented) The solid dosage form of claim 19, wherein the multilayer tablet is coated with a rate controlling polymer.

21. (Currently Amended) The solid dosage form according to claim 14, wherein the nanoparticulate drug, at least one auxiliary excipient, and the **high molecular weight** rate controlling polymer material are combined into a multiparticulate form.

22. (Previously Presented) The solid dosage form according to claim 21, wherein the multiparticulate form comprises discrete particles, pellets, minitabets, or combinations thereof.

23.-24. (Cancelled)

25. (Previously Presented) The solid dosage form according to claim 22 wherein the discrete particles or pellets are compressed into tablet form.

26. (Previously Presented) The solid dosage form according to claim 25 wherein the tablet form is coated with a rate controlling polymer material.

27. (Previously Presented) The solid dosage form according to claim 22 wherein the discrete particles or pellets are compressed into a multilayer tablet.

28. (Previously Presented) The solid dosage form according to claim 27 wherein the multilayer tablet is coated with a rate controlling material.

29. (Previously Presented) The solid dosage form according to claim 14 wherein the tablet further comprises an osmagent added to the controlled release composition to form an admixture and a semi-permeable membrane; the semi-permeable membrane surrounding the admixture and being permeable to aqueous media, but impermeable to the poorly soluble

drug compound or pharmaceutically acceptable salt thereof and the semi-permeable membrane defining an orifice therein.

30. (Currently Amended) A method of preparing a solid dose controlled release nanoparticulate formulation comprising:

- (a) combining a nanoparticulate composition of a nanoparticulate drug to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate drug, wherein the composition has an effective average particle size of less than about 1000 nm, wherein at least 50% of the drug particles have an average particle size of less than about 1000 nm when measured by light scattering techniques, and at least one suitable **high molecular weight** rate-controlling polymer; and
- (b) forming a solid dose of the mixture from step (a), wherein the solid dose formulation has a controlled release of the nanoparticulate drug following administration for a time period ranging from about 2 to about 24 hours.

31. (Previously Presented) The method of claim 30, wherein the effective average particle size of the nanoparticulate drug particles is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm, wherein at least 50% of the drug particles have an average particle size of less than about 800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

32. (Currently Amended) The method of claim 30, wherein the concentration of the **high molecular weight rate-controlling** polymer is from about 5 to about 95% (w/w).

33. (Currently Amended) The method of claim 32, wherein the concentration of the **high molecular weight rate-controlling** polymer is from about 10 to about 65% (w/w).

34. (Currently Amended) The method of claim 31, comprising adding water to the nanoparticulate drug, surface stabilizer, and **high molecular weight** rate-controlling polymer to form granules prior to step (b).

35. (Previously Presented) A method of treating a mammal comprising administering to the mammal an effective amount of a solid dose controlled release nanoparticulate formulation wherein:

- (a) the formulation comprises nanoparticulate drug particles to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate drug, wherein the nanoparticulate drug particles have an effective average particle size of less than about 1000 nm, wherein at least 50% of the drug particles have an average particle size of less than about 1000 nm when measured by light scattering techniques, and at least one suitable rate-controlling polymer; and
- (b) the formulation has a controlled release of the nanoparticulate drug following administration for a time period ranging from about 2 to about 24 hours.

36. (Previously Presented) The method of claim 35, wherein the effective average particle size of the nanoparticulate drug particles is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm, wherein at least 50% of the drug particles have an average particle size of less than about 800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

37. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508®, dialkylesters of

sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl -D-glucopyranoside, n-decyl -D-maltopyranoside, n-dodecyl -D-glucopyranoside, n-dodecyl -D-maltoside, heptanoyl-N-methylglucamide, n-heptyl--D-glucopyranoside, n-heptyl -D-thioglucoside, n-hexyl -D-glucopyranoside, nonanoyl-N-methylglucamide, n-nonyl -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl--D-glucopyranoside, and octyl -D-thioglucopyranoside.

38. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

39. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelastine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide,

glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

40. (Previously Presented) The solid dose controlled release nanoparticulate composition of claim 1, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

41. (Previously Presented) The solid dosage form of claim 14, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl -D-glucopyranoside, n-decyl -D-maltopyranoside, n-dodecyl -D-glucopyranoside, n-dodecyl -D-maltoside, heptanoyl-N-methylglucamide, n-heptyl--D-glucopyranoside, n-heptyl -D-thioglucoside, n-hexyl -D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl--D-glucopyranoside, and octyl -D-thioglucopyranoside.

42. (Previously Presented) The solid dosage form of claim 14, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

43. (Previously Presented) The solid dosage form of claim 14, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelastine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalixin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

44. (Previously Presented) The solid dosage form of claim 14, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

45. (Previously Presented) The method of claim 30, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl -D-glucopyranoside, n-decyl -D-maltopyranoside, n-dodecyl -D-glucopyranoside, n-dodecyl -D-maltoside, heptanoyl-N-methylglucamide, n-heptyl--D-glucopyranoside, n-heptyl -D-thioglucoside, n-hexyl -D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl--D-glucopyranoside, and octyl -D-thioglucopyranoside.

46. (Previously Presented) The method of claim 30, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics,

immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

47. (Previously Presented) The method of claim 30, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelastine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalexin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole, flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

48. (Previously Presented) The method of claim 30, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

49. (Previously Presented) The method of claim 35, wherein the surface stabilizer is selected from the group consisting of gelatin, casein, lecithin, dextran, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose,

magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, poloxamers, poloxamines, Tetronic 1508[®], dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a mixture of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), Crodestas SL-40[®], SA9OHCO, decanoyl-N-methylglucamide, n-decyl -D-glucopyranoside, n-decyl -D-maltopyranoside, n-dodecyl -D-glucopyranoside, n-dodecyl -D-maltoside, heptanoyl-N-methylglucamide, n-heptyl--D-glucopyranoside, n-heptyl -D-thioglucoside, n-hexyl -D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl -D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl--D-glucopyranoside, and octyl -D-thioglucopyranoside.

50. (Previously Presented) The method of claim 35, wherein the drug is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antiasthma agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antitussives, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, antipyretics, immunosuppressants, immunostimulants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, bronchodilators, cardiac inotropic agents, chemotherapeutics, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, proteins, polypeptides, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, hormones, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vaccines, vasodilators, and xanthines.

51. (Previously Presented) The method of claim 35, wherein the drug is selected from the group consisting of alprazolam, amiodarone, amlodipine, astemizole, atenolol, azathioprine, azelatine, beclomethasone, budesonide, buprenorphine, butalbital, carbamazepine, carbidopa, cefotaxime, cephalixin, cholestyramine, ciprofloxacin, cisapride, cisplatin, clarithromycin, clonazepam, clozapine, cyclosporin, diazepam, diclofenac sodium, digoxin, dipyridamole, divalproex, dobutamine, doxazosin, enalapril, estradiol, etodolac, etoposide, famotidine, felodipine, fentanyl citrate, fexofenadine, finasteride, fluconazole,

flunisolide, flurbiprofen, fluvoxamine, furosemide, glipizide, gliburide, ibuprofen, isosorbide dinitrate, isotretinoin, isradipine, itraconazole, ketoconazole, ketoprofen, lamotrigine, lansoprazole, loperamide, loratadine, lorazepam, lovastatin, medroxyprogesterone, mefenamic acid, methylprednisolone, midazolam, mometasone, nabumetone, naproxen, nicergoline, nifedipine, norfloxacin, omeprazole, paclitaxel, phenytoin, piroxicam, quinapril, ramipril, risperidone, sertraline, simvastatin, terbinafine, terfenadine, triamcinolone, valproic acid, zolpidem, and pharmaceutically acceptable salts thereof.

52. (Previously Presented) The method of claim 35, wherein the drug is selected from the group consisting of naproxen, glipizide, and nifedipine.

53. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 1, wherein the nanoparticulate drug composition and **high molecular weight** rate-controlling polymer exist in a form selected from the following group:

- (a) a tablet of the nanoparticulate drug composition coated with the **high molecular weight** rate-controlling polymer,
- (b) a compressed matrix comprising the nanoparticulate drug composition dispersed in the **high molecular weight** rate-controlling polymer,
- (c) a compressed matrix comprising the nanoparticulate drug composition dispersed in the **high molecular weight** rate-controlling polymer, which matrix is coated with the **high molecular weight** rate-controlling polymer,
- (d) a multilayer tablet of the nanoparticulate drug composition, which tablet is coated with the **high molecular weight** rate-controlling polymer,
- (e) a multilayer tablet of the nanoparticulate drug composition dispersed in the **high molecular weight** rate-controlling polymer, which tablet optionally is further coated with the rate-controlling polymer, and
- (f) a multiparticulate form comprising discrete particles, pellets, and/or mini-tablets.

54. (Currently Amended) The solid dose controlled release nanoparticulate composition of claim 10, wherein the **high molecular weight** rate-controlling polymer is polyethylene oxide (PEO) or polyvinyl acetate phthalate.